REMARKS/ARGUMENTS

I. STATUS OF THE APPLICATION

Claims 151-153, 156, 160-161, 167-170, and 174-210 are presently pending and stand rejected. By way of this response, claims 152 and 187-210 have been amended. Written support for the amended claims may be found in the specification at least at page 21, lines 7 & 8; pages 88-89 and 96-110; page 127, line 14-30; and pages 134-138. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

II. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claim 152 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Without admitting or conceding in any manner that rejected claim 152 fails to comply with 35 U.S.C. § 112, second paragraph, and solely to expedite the prosecution of the present application, claim 152 has been amended to clarify the relationship between omeprazole and esomeprazole by reciting that the "isomer of" omeprazole is esomeprazole. Applicant respectfully submits that this rejection is now moot, and that no new matter has been presented by way of this amendment. Withdrawal of the rejections of claim 152 under 35 U.S.C. § 112, second paragraph is respectfully requested.

III. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAW

Claims 151-153, 156, 160-161, 167-170, and 174-210 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection. Applicant hereby incorporates by reference its previous response to a similar rejection regarding the enablement requirement in this application: Serial No. 10/722,184 – Amendment and Response to January 9, 2007 Office Action.

The Examiner states:

> The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.
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> * * *
>
> There is no evidence in the record that a composition meeting the ratio requirement without at least a therapeutically effective dose of omeprazole can achieve such a blood level. In addition, there is no evidence in the record that such blood level can be obtained when the drug to buffering agent ratio varied beyond the single 40 mg omeprazole-20 mg [sic] sodium bicarbonate composition.
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> * * *
>
> Nor was there any support that the wide varieties of basic agent of claim 161 would function in analogous manner in providing serum absorption as the 40 mg omeprazole/20 mg [sic] sodium bicarbonate coadministration.

Without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph, and solely to expedite the prosecution of the present application, claims 187-210 have been amended. Accordingly, Applicant submits that this rejection is now moot and respectfully requests that this rejection be withdrawn in light of the below arguments and amendments, which are made. Claim 187 has been amended as an independent claim comprising a non-enteric coated omeprazole or an isomer, tautomer, free base, or salt thereof, having a concentration between about 20 mg to about 40 mg, at least one buffering agent in an amount of about 0.2 mEq to 5 mEq per 2 mg of omeprazole, and at least one thickening agent, wherein the composition is in a form of a powder for suspension that is storage stable at room temperature and further having a functional limitation. Claims 188-210 have been amended as dependent claims of Claim 187. Examples XI, XV and XVI, at pages 88-89 and 96-110 of the specification, clearly describe and enable the claimed invention. One skilled in the art would be able to modify the teachings of the ranges in the disclosure to make and use the claimed invention.

Claim 151 requires a ratio of 0.2 mEq to 5 mEq of a buffering agent per 2 mg omeprazole. This ratio or buffering range is related to the pKa of a given proton pump inhibitor. Ideally, the lower limit of the buffering range is calculated as the pKa of a given proton pump inhibitor + 0.7 log value (or greater) stated on page 112, lines 8 and 9, of the specification. The term "milliequivalents" or "mEq" inherently relates to the acid neutralizing capacity of a

buffering agent and, therefore, the skilled artisan would certainly understand how to practice this element of the invention without undue experimentation. Indeed, the mEq or acid neutralizing capacity can be readily calculated for each of the claimed buffering agents listed in claim 161 according to the equation described on page 127, lines 14-30, of the specification. Given the proton pump inhibitor, the mEq of the buffering agent, and the teachings of the specification, the skilled artisan could tailor a buffering agent dose for any substituted benzimidazole proton pump inhibitor to promote proton pump inhibitor efficacy in an oral administration. Examples in Section H, at pages 134– 138 of the specification, clearly describe and enable the use of the various buffering agents in the claimed invention. In accordance with the teachings of the specification, one skilled in the art would be able to take into consideration the different pH, ionic strength, and buffering capacity of the various buffering agents when determining the desired buffering range for a given proton pump inhibitor without undue experimentation.

Further, the pharmacokinetic limitation ("average plasma concentration of the omeprazole of at least about 0.1 μg/ml at any time within about 30 minutes after administration") is a functional limitation, which is understood in the art and is permissible under applicable precedent. For example, in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 68 U.S.P.Q.2d 1865, 1873 (Fed. Cir. 2003), the Federal Circuit stated, "a functional limitation covers all embodiments performing the recited function." Here, although various buffering agents may differ by solubility (and hence rate of acid neutralization), pH, ionic strength, and buffering capacity, the functional pharmacokinetic language limits the claim to those buffering agents (or mixtures thereof) that provide the claimed result. *See also In re Swinehart*, 169 U.S.P.Q. 226 (C.C.P.A. 1971). In light of the current amendments to the claims and the foregoing arguments, Applicant respectfully requests withdrawal of this rejection

IV. OBVIOUSNESS-TYPE DOUBLE PATENTING

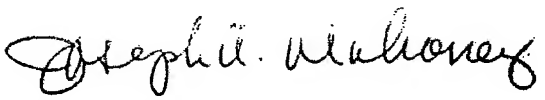
The claims stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the issued claims of U.S. 6,699,885 and 6,489,346, and the copending claims of SN 10/641,732 as described in the Office Action. Without admitting or conceding in any manner that the rejected claims are unpatentable over the above-referenced issued or co-pending claims, and solely to expedite the prosecution of the present application, applicant will submit a terminal disclaimer upon the indication of allowable subject matter.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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